UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,981	06/29/2006	Keyvan Behnam	2004367-0078	2245

25763 7590 07/21/2010

DORSEY & WHITNEY LLP
INTELLECTUAL PROPERTY DEPARTMENT
SUITE 1500
50 SOUTH SIXTH STREET
MINNEAPOLIS, MN 55402-1498

EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
07/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,981	BEHNAM ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *1-30,47 and 49-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-46,48,73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20091222, 20100506; 2010525*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response of 5/6/2010 has been received and entered into the application file. Claims 31-36, 43 and 45 have been amended, new claims 73 and 74 have been added.

Claims 1-72 remain pending in the instant application, of which claims 1-30, 47 and 49-72 are withdrawn from consideration as being directed to non-elected inventions, pursuant to 37 CFR 1.142(b). Election was made **without** traverse on 7/17/2009. Claims 31-46 and 48 have been considered on the merits.

Applicants' arguments have been fully considered and will each be addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Formal Matters

It is noted that the amendment to claim 32 is not in proper form according to 37 CFR 1.121(c), which requires text to be deleted to be marked with a strike-through, unless the text to be deleted is less than five characters, in which case it may be enclosed in double brackets. In claim 32, in the third line, the term "differentation" is enclosed in single brackets, the term should be 'struck-through' (~~differentation~~). In order to provide compact prosecution the minor error will not cause the amendment to be considered non-compliant, but future errors may necessitate a notice of non-compliant amendment.

For purposes of examination, the term "[differentation]" in the 3rd line of claim 32 is being considered to be deleted.

Drawings

The drawings received on 5/6/2010 (specifically the second set of drawings received 5/6/2010) have been reviewed and are accepted. The objection to the drawings is withdrawn.

Claim Objections

The amendment to claim 43 obviates the objection of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The amendments to the claims have obviated the rejections under 35 USC 112, second paragraph, previously of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Regarding the rejection of record over O'Leary et al:

The amendments to the claims, specifically the amendment to claim 31 limiting the treatment or condition to which the bone matrix is exposed to be a cleavage agent selected from collagenase and CNBr, obviates the rejection under 35 USC 102(b) as being anticipated by O'Leary et al.

Regarding the rejection of record over Landesman et al:

Applicants have traversed the rejection of record on the grounds that the bone matrix composition treated by collagenase in the disclosure of Landesman et al exhibits decreased osteoinductive activity, which is in contrast to that which is currently claimed ("increased biological activity"). Applicant further

argues that the collagenase digestion method of Landseman et al and the instant application are not identical, and thus the modified bone matrices of Landesman et al and the instant claim cannot be held to inherently have the same properties.

In response, Applicants' arguments have been fully considered and are found persuasive in part. Upon review it is noted that there are slight differences between the collagenase digestion method of Landesman et al and the method carried out in Example 10 of the instant application (which method yields a bone matrix having increased osteoinductive potential, as evidenced by increased alkaline phosphatase activity in cells cultured with the modified bone matrix, compared to untreated bone matrix). For example, Landesman et al do not disclose the amount of or source of the collagenase enzyme used (Applicants report using 80 U/g of bacterial collagenase), Landesman et al report the temperature at which the digestion was carried out as room temperature (22°C)(Applicants report carrying out digestion at 37°C), Landesman et al utilize collagenase in a PBS buffer (Applicants report utilizing 50 mM Tris-HCl buffer), and finally, Landesman et al do not report stirring the digested bone matrix for 1 hour in 45 mL of 0.1N acetic acid, followed by washing with water and neutralizing with PBS (as is reported by Applicants). Because the procedures by which the bone matrices were enzymatically digested are not identical, the resulting products cannot be held to inherently have the same characteristics. Therefore, the rejection based on the bone matrix of Landesman et al inherently having the same increased osteoinductive activity as that currently claimed is withdrawn.

However, while the bone matrix of Landesman et al cannot be held to have the same increased osteogenic activity as the bone matrix produced by the method of Example 10 of the specification, and encompassed by the instant claims, it is submitted that claim 31 is not limited to increased *osteoinductive* activity compared to an unmodified control matrix, but rather claim 31 encompasses a modified bone matrix demonstrating an increase in *any* biological activity compared to an unmodified control matrix. Because the collagenase-digested matrix of Landesman et al is reported to elicit greater invasion by

fibroblast-like mesenchymal cells as compared to control, unmodified matrices (See Landesman et al, pg. 350, paragraph spanning columns 1-2), the collagenase-treated bone matrix of Landesman et al is considered to have an increased *chemotactic* activity compared to the untreated matrices. Chemotactic activity is an example of a biological activity, and is a recited species of claim 38, therefore the rejection over Landesman et al is maintained over at least some of the instant claims.

Claims 31, 38-40 and 48 stand rejected under 35 U.S.C. 102(b) as being anticipated by Landesman et al (Calcified Tissue International, 1989). New claim 73 is also being included in this grounds of rejection.

Landesman et al disclose demineralized bone matrix which has been subjected to collagenase treatment (See Landesman et al, Pg. 349, Materials and Methods: "Preparation of Demineralized Bone Matrix" and "Enzymatic Treatment of Bone Matrix"). The collagenase-treated demineralized bone matrix is considered to read on a modified bone matrix. The collagenase reads on a cleavage agent.

Upon implantation *in vivo* the collagenase-treated demineralized bone matrix was invaded by fibroblast-like mesenchymal cells, whereas untreated control demineralized bone matrices were not (See Landesman et al, Pg. 350, paragraph spanning columns 1-2 and Fig. 1A-1D). Therefore the collagenase-treated demineralized bone matrix exhibited greater chemotaxis-inducing activity than the unmodified control matrix, as evidenced by the greater invasion by fibroblast-like mesenchymal cells. Chemotaxis-inducing activity (chemotactic activity) is an example of a biological activity. Therefore the collagenase-treated demineralized bone matrix of Landesman et al anticipates the modified bone matrix of current claims 31, 38-40 and 73.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Regarding the rejection of record over O'Leary et al:

The amendments to the claims obviates the rejection under 35 USC 102(b) as being anticipated by O'Leary et al, as discussed above. Because O'Leary et al does not properly anticipate claim 31, the obviousness rejection of claim 37 based on O'Leary et al necessarily falls. The rejection is withdrawn.

Regarding the rejection of record over Landesman et al:

Applicants have traversed the rejection of record on the grounds that the bone matrix composition treated by collagenase in the disclosure of Landesman et al exhibits decreased osteoinductive activity, which is in contrast to that which is currently claimed ("increased biological activity"). Applicants further argue that because Landesman et al specifically teaches results in contrast to that which is claimed, one would not have had a reasonable expectation that collagenase treatment would successfully increase biological activity, as claimed.

In response, Applicants' arguments have been fully considered, and are found persuasive. Though Landesman et al does properly anticipate claim 31, for the reasons discussed above, because the collagenase-treated bone matrix of Landesman et al does not exhibit improved osteogenic properties, one having ordinary skill in the art would not have been motivated to carry out the collagenase-treatment method of Landesman et al on human bone, as the final product is not desirable.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicants have responded to the provisional obviousness-type double patenting rejection by requesting the provisional rejection to be held in abeyance until the time that subject matter in either application is indicated allowable.

This response is found acceptable. The provisional rejection stands at this time, but will be reviewed as prosecution in both cases continues. A full traversal or filing of a terminal disclaimer will not be required until subject matter in either application is indicated allowable.

Claims 31, 38-40, 42, 43 and 48 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 73, 77, 83 and 84 of copending Application No. 12/140,025 (hereafter application '025). Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims of application '025 anticipate the subject matter.

The osteoinductive composition of copending claim 73 is an at least partially demineralized bone which has been treated to increase the osteoinductive activity of the bone as compared to untreated

demineralized bone matrix. The increase in osteoinductive activity reads on an increase in biological activity, as required by claim 31, and specifically on an increase in osteoinductive activity, as required by claim 38. The osteoinductive composition comprises at least partially demineralized bone matrix, which reads on the at least partially demineralized bone matrix and at least partially demineralized bone section of claims 39 and 40, respectively.

Copending claim 77 states the osteoinductive composition has increased solubility as compared to untreated demineralized bone matrix, thereby anticipating instant claim 43.

Copending claim 83 states the osteoinductive composition is formed into an implant, which reads on a device comprising the osteoinductive composition (which reads on the modified bone matrix of claim 31), thereby anticipating claim 48.

Copending claim 84 states the osteoinductive composition may further comprise a carrier, thereby anticipating instant claim 42.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Grounds of Rejection: Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a new grounds of rejection, necessitated by the amendment limiting the treatment or condition to exposure to a cleavage agent selected from the group consisting of collagenase and CNBr.

Claims 31, 37-46, 48, 73 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification fails to provide support for the full scope of the invention.

Independent claim 31 is directed to a modified bone matrix, wherein the modified bone matrix has been exposed to a cleavage agent selected from collagenase and CNBr, and wherein the modified bone matrix has a level of at least one biological activity which is increased relative to the level in an unmodified control bone matrix.

Dependent claim 38 defines the at least one biological activity as being selected from the group consisting of osteoinductive activity, osteogenic activity, chondrogenic activity, wound healing activity, neurogenic activity, contraction-inducing activity, mitosis-inducing activity, differentiation-inducing activity, chemotactic activity, angiogenic activity, vasculogenic activity, exocytosis-inducing activity, and endocytosis-inducing activity.

The specification does provide sufficient evidence and guidance to enable one having ordinary skill in the art to produce a modified bone matrix which has an increased osteogenic or chondrogenic activity compared to unmodified control bone matrix by exposing bone matrix to a cleavage agent. However, the specification does not provide sufficient evidence or guidance to enable one having ordinary skill in the art to produce a modified bone matrix which has an increased level of any biological activity compared to unmodified control bone matrix by exposing bone matrix to a cleavage agent.

The claims addressed in this rejection are generic to the biological activity which is increased in the modified bone matrix as compared to unmodified bone matrix, for the reasons discussed below, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims include bone matrix exposed to a cleavage agent, wherein the modified bone matrix demonstrates an increase in *any and all* biological activities, compared to untreated bone matrix.

Applicants' specification provides a working example whereby demineralized bone matrix is treated with collagenase to produce a modified demineralized bone matrix. The modified demineralized

bone matrix was shown to significantly enhance alkaline phosphatase activity in C2C12 myoblast cells in culture over control demineralized bone matrix, and even over BMP-treated demineralized bone matrix (See Example 10 & Figs. 2-3). Alkaline phosphatase is a recognized marker of osteogenesis and chondrogenesis; therefore, by demonstrating that the collagenase-digested (modified) demineralized bone matrix increased alkaline phosphatase expression in cultured cells compared to control demineralized bone matrix, Applicants do support that the collagenase-modified demineralized bone matrix has enhanced osteogenic and chondrogenic activity over unmodified control demineralized bone matrix.

While the results provided by Applicants with regards to increased osteogenic and chondrogenic potential of collagenase-treated DBM (as evidenced by increased alkaline phosphatase expression in cells cultured in the presence of the modified bone matrix) are impressive, they are insufficient to support the full scope of the claims, specifically that bone matrices modified by exposure to a cleavage agent have a level of any biological activity greater than that exhibited in unmodified control bone matrices.

Applicants have tested expression of a single marker, alkaline phosphatase, in an *in vitro* culture with one cell line. While alkaline phosphatase is expressed early in osteogenesis and chondrogenesis it is not expressed in other differentiation pathways, such as neurogenesis, nor is it a recognized marker of wound healing, angiogenesis, vasculogenesis, mitosis, exocytosis or endocytosis, nor is it highly expressed in the beginning stages of contractions. For the reasons discussed above under 35 USC 102(b) Landesman et al can be relied upon to show a correlation between collagenase treatment and chemotaxis of fibroblast-like mesenchymal cells.

There are no teachings or guidance provided in the specification with regards to a connection between cleavage agents collagenase and/or CNBr and any of the recited biological activities except osteoinduction and chondroinduction. Rather, these biological activities are vaguely suggested as possible effects. However, given the breadth of the claims, the variety of biological activities claimed, and the lack of supporting evidence, teachings or guidance for any of the biological activities beyond

osteoinduction and chondroinduction (as evidenced by increased induction of alkaline phosphatase expression), the skilled artisan would be faced with the impermissible burden of undue experimentation in order to make a modified bone matrix having the full scope of biological properties encompassed by the claims. Accordingly, claims 31, 37-46, 73 and 74 are deemed properly rejected.

Claims 31-46 and 48 are rejected under 35 U.S.C. 112, first paragraph, because the specification fails to provide support for the full scope of the invention.

Independent claim 31 is directed to a modified bone matrix, wherein the modified bone matrix has been exposed to a cleavage agent selected from collagenase and CNBr, and wherein the modified bone matrix has a level of at least one biological activity which is increased relative to the level in an unmodified control bone matrix.

The specification does provide sufficient evidence and guidance to enable one having ordinary skill in the art to produce a modified bone matrix which has an increased osteogenic or chondrogenic activity compared to unmodified control bone matrix by subjecting bone matrix to collagenase treatment. However, the specification does not provide sufficient evidence or guidance to enable one having ordinary skill in the art to produce a modified bone matrix which has an increased level of any biological activity compared to unmodified control bone matrix by subjecting a bone matrix to collagenase or CNBr treatment.

The claims addressed in this rejection are directed to a modified bone matrix which has been exposed to either collagenase or CNBr and as result exhibits an increased level of at least one biological activity as compared to unmodified bone matrix. For the reasons discussed below, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims include bone matrix modified by either collagenase *or* CNBr, wherein the modified bone matrix demonstrates an increase in any and all biological activities, compared to untreated bone matrix.

Applicants' specification provides a working example whereby demineralized bone matrix is treated with collagenase to produce a modified demineralized bone matrix. The modified demineralized bone matrix was shown to significantly enhance alkaline phosphatase activity in C2C12 myoblast cells in culture over control demineralized bone matrix, and even over BMP-treated demineralized bone matrix (See Example 10 & Figs. 2-3). Alkaline phosphatase is a recognized marker of osteogenesis and chondrogenesis; therefore, by demonstrating that the collagenase-digested (modified) demineralized bone matrix increased alkaline phosphatase expression in cultured cells compared to control demineralized bone matrix, Applicants do support that the collagenase-modified demineralized bone matrix has enhanced osteogenic and chondrogenic activity over unmodified control demineralized bone matrix.

While the results provided by Applicants with regards to increased osteogenic and chondrogenic potential of collagenase-treated DBM (as evidenced by increased alkaline phosphatase expression in cells cultured in the presence of the modified bone matrix) are impressive, they are insufficient to support the full scope of the claims, specifically that either collagenase *or* CNBr can be used as the cleavage agent to achieve the modified bone matrix.

Applicants' results reported in Example 10 are impressive because at the time the invention was made, the art taught that collagenase and CNBr generally abolished osteogenic activity of bone matrices (See Landesman et al, abstract & Oppermann et al, USP 5,354,557, col. 27, ln 23-26), Applicants' evidence showing collagenase-treated demineralized bone matrix had increased capacity to induce expression of alkaline phosphatase (an early marker of both osteogenesis and chondrogenesis) therefore is evidence of unexpected results- for collagenase treated bone matrices. Applicants provide no evidence or working examples wherein cyanogen bromide is used as a cleavage agent to modify bone matrices, much

less evidence that cyanogen bromide-treated bone matrices had increased ability to induce alkaline phosphatase (or any other biological marker) compared to untreated bone matrices. Teachings and guidance as to use of CNBr for the cleavage agent is limited to the statement that CNBr is one of the contemplated chemical agents which the bone matrix may be exposed to (See ¶0011, ¶0017, ¶0073 and ¶0086 of the PGPub).

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, discussed above, which teaches that CNBr specifically abolishes osteogenic activity in bone matrices, and the limited teachings with regards to use of CNBr within the specification, the Office would require appropriate disclosure to support the contention that CNBr-treated bone matrices have increased osteogenic (or any other biological) activity levels compared to untreated bone matrices. The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Thus, due to the clear teaching away in the art regarding the effect of CNBr on bone matrix biological activity, the current specification would have to provide greater amounts of teachings and guidance directed to methods of carrying out the claimed invention.

Therefore, due to the sum of all the aforementioned factors, one of ordinary skill in the art, at the time the invention was made, would not expect successfully producing a modified bone matrix having increased levels of osteogenic activity, or any other biological activity, by treating a bone matrix with CNBr. Accordingly, claims 31-46 are deemed properly rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651